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09/178,126	10/23/1998	TIMOTHY STIVLAND	1001.1294101	4007

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EXAMINER
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LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/03/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/178,126

Applicant(s)

STIVLAND ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on August 15, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 49-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. Claims 49-56, 61-64, 67, 69 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510.

Sirhan et al. discloses the invention substantially as claimed. More specifically, Sirhan et al. discloses a first tube (32) including an inflation lumen (36 and proximal portion of 37) in fluid communication with a dilatation balloon (distal portion of 37), an inside wall surface, and an outside wall surface, said first tube having an orifice (42) in a proximal portion of said first tube; a second tube (33) inserted through, and extending distally from said orifice inside said inflation lumen, said second tube having a length, a lumen therethrough, a proximal portion, an inside wall surface and an outside wall surface, see Figure 16; and a bonding region wherein said second tube outside wall surface is bonded to said first tube outside wall surface by re-flow of the first and second tube outside wall surfaces, see column 6, lines 1-3 and see column 3, lines 17-23, and column 7, line 59 – column 8, line 16, said second tube inside wall surface

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being formed of a second, lubricous material for a majority of said second tube length, said first tube wall having a layer of a first, flexible material extending for a majority of said first tube length, said first material being different from said second material, see column 9, lines 46-53.

As to claim 50, said bonding region is proximate said orifice, see column 5, lines 52-56, and see Figure 6.

As to claim 51, said bonding region includes bonding between said first tube inside surface and said second tube outside surface distal of said orifice, see column 3, lines 17-23.

As to claim 52, said second tube inside and outside wall surfaces are formed of said second material, see column 9, lines 46-53.

As to claim 53, said second tube wall is formed of substantially said second material therethrough, see column 9, lines 46-53.

As to claim 54, said first tube inside surface is formed of said second material proximate said bonding region, see column 9, lines 46-53.

As to claim 55, said first tube has said second material disposed over most of said first tube inside surface proximate said bonding region and distal of said bonding region, see column 9, lines 46-53.

As to claims 61-64, Sirhan et al. disclose that the catheter shaft, including the inner and outer tubular members may be made from polymeric materials such as polyethylene, polyamide, etc and other suitable polymeric materials, see column 9, lines 46-53.

As discussed above, Sirhan discloses a bonding region wherein said second tube outside wall surface is bonded to said first tube outside wall surface by re-flow of the first and second tube outside wall surfaces, see column 6, lines 1-3, see column 3, lines 17-23, and column 7, line 59 – column 8, line 16.

In the alternative, Sirhan discloses that the second and first tubes are bonded, see column 6, lines 1-3, and it would have been obvious to one of ordinary skill in the art to provide a bond wherein said second tube outside wall surface is bonded to said first tube outside wall surface by re-flow of the first and second tube outside wall surfaces, as taught in column 3, lines 17-23, and column 7, line 59 – column 8, line 16.

However, Sirhan et al. does not disclose a tie-layer disposed between the inside and outside layers, wherein said intermediate tie-layer is disposed at an angle relative to a tube wall of said first tube.

Fontirroche discloses a tie-layer, comprising Plexar™ for example, may be used to bond together dissimilar outer plastic layers, see column 2, lines 35-38. Moreover, Fontirroche discloses that the chemical bonding between two catheter layers can be subsequently heat treated, see column 3, lines 17-20. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to bond the plastic layers of the Sirhan et al. catheter by using Plexar as a tie-layer to bond the plastic layers, as taught by Fontirroche.

Moreover, the bonding portion, i.e., the tie-layer portion, in the Sirhan et al. catheter is considered to be disposed between a proximal portion and a distal portion of

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a tube wall of said first tube, as claimed by Applicant. (Applicant has not specifically defined where the proximal portion and distal portion begins and ends.)

Also, the tie-layer is considered to be disposed at an angle relative to said tube wall. (Applicant has not specifically defined whether the angle is 90 degrees or 180 degrees, for example.)

2. Claims 57, 66, 68, 70 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510, as applied to claims 56, 65, 69, 71, 73 above, and further in view of Berg et al., 5,792,116. Sirhan et al. in view of Fontirroche et al. discloses the invention substantially as claimed, see above with respect to claim 56. More specifically, Sirhan discloses that polymeric materials may be used to form the inner or outer tubular members, see column 9, lines 46-53. However, Sirhan et al. in view of Fontirroche et al. does not disclose an outside layer of PEBA.

Berg et al. however discloses PEBA as a known polymer used to form catheters, see column 6, line 8. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device.

3. Claims 58, 59, 65 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, , in view Fontirroche et al., 5,538,510, and further in view of Javier, Jr. et al., 6,093,177.

Sirhan et al. in view of Fontirroche et al. disclose the invention substantially as claimed (see above), except for the first tube having an inside surface formed of said second material proximate said bonding region and said inside surface formed of said first material distal of said bonding region.

However, Javier, Jr. et al. discloses that relative flexibility or the inverse stiffness of the various shaft sections of a catheter may be achieved by selecting different materials. "[T]he material used in the intermediate shaft section may be inherently more flexible than a different material used in the proximal or distal shaft sections", see column 2, lines 5-15. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide different materials on different shaft sections of the Sirhan et al. catheter in order to achieve the desired flexibility of the catheter shaft sections as may be necessary for a particular treatment of a patient

4. Claims 60 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view of Javier, Jr. et al., 6,093,177, further in view of Fontirroche et al., 5,538,510, as applied to claim 59, and further in view of Berg et al., 5,792,116.

Although Sirhan in view of Javier and further in view of Fontirroche disclose the invention substantially as claimed, they however do not disclose the first tube being formed of PEBA distal of said tie-layer.

Berg et al. however discloses PEBA as a known polymer used to form catheters, see column 6, line 8. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device.

5. Claims 75-82, 87-90, 93, 95 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510, and further in view of Ressemann et al., 5,571,087.

Sirhan et al. discloses the invention substantially as claimed. More specifically Sirhan et al. discloses a first tube (32) including an inflation lumen (36 and proximal portion of 37) in fluid communication with a dilatation balloon (distal portion of 37), an inside wall surface, and an outside wall surface, said first tube having an orifice (42) in a proximal portion of said first tube; a second tube inserted through, and extending distally from said orifice inside said inflation lumen, said second tube having a length, a lumen therethrough, a proximal portion, an inside wall surface and an outside wall surface, see Figure 16; and a bonding region wherein said second tube outside wall surface is bonded to said first tube outside wall surface by re-flow of the first and second tube outside wall surfaces, see column 3, lines 17-23, and column 7, line 59 – column 8, line 16, said second tube inside wall surface being formed of a second, lubricous material for a majority of said second tube length, said first tube wall having a layer of a first, flexible material extending for a majority of said first tube length, said first material being different from said second material, see column 9, lines 46-53.



As to claim 76, said bonding region is proximate said orifice, see column 5, lines 52-56, and see Figure 6.

As to claim 77, said bonding region includes bonding between said first tube inside surface and said second tube outside surface distal of said orifice, see column 3, lines 17-23.

As to claim 78, said second tube inside and outside wall surfaces are formed of said second material, see column 9, lines 46-53.

As to claim 79, said second tube wall is formed of substantially said second material therethrough, see column 9, lines 46-53.

As to claim 80, said first tube inside surface is formed of said second material proximate said bonding region, see column 9, lines 46-53.

As to claims 81, 89, said first tube has said second material disposed over most of said first tube inside surface proximate said bonding region and distal of said bonding region, see column 9, lines 46-53.

As to claims 83, 87, 88, 90, Sirhan et al. disclose that the catheter shaft, including the inner and outer tubular members may be made from polymeric materials such as polyethylene, polyamide, etc and other suitable polymeric materials, see column 9, lines 46-53.

The third tube, the first tube being disposed distal of the third tube, is disclosed. (The third tube is considered to be a proximal section of said first tube, or alternatively, a proximal section of said second tube.)

However, Sirhan et al. does not disclose a tie-layer disposed between the inside and outside layers, wherein said intermediate tie-layer is disposed at an angle relative to a tube wall of said first tube.

Fontirroche discloses a tie-layer, comprising Plexar™ for example, may be used to bond together dissimilar outer plastic layers, see column 2, lines 35-38. Moreover, Fontirroche discloses that the chemical bonding between two catheter layers can be subsequently heat treated, see column 3, lines 17-20. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to bond the plastic layers of the Sirhan et al. catheter by using Plexar as a tie-layer to bond the plastic layers, as taught by Fontirroche.

However, Sirhan et al. does not teach a core wire extending distally from the third tube into the first tube.

Ressemann et al. however teaches a catheter (20) having a section (22) being relatively stiff and the distal shaft section (23) being relatively flexible, the configuration of which will tend to bend or buckle in the relatively flexible area as an attempt is made to advance the catheter (2) through a vasculature, the catheter tending to kink at the transition section. Ressemann et al. teaches that a core wire (25), see column 7, lines 26-27, in the catheter provides two functions: to provide axial or column strength to the distal shaft section (24); and to prevent kinking of the distal shaft section (24). It would have been obvious to provide a core wire, as taught by Ressemann et al., in the Sirhan et al.-in-view-of-Fontirroche device in order to provide axial strength to the distal shaft

section, and/or to prevent kinking of the distal shaft section, which may comprise a different material from a proximal section.

6. Claim 83, 94, 96 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., in view Fontirroche et al., 5,538,510,, and further in view of Ressemann et al., and further in view of Berg et al., 5,792,116. Sirhan et al., Fontirroche et al., and Ressemann et al. disclose the invention substantially as claimed (see above), except for the outside layer being comprised of PEBA.

Berg et al. however discloses PEBA as a known polymer used to form catheters, see column 6, line 8. Since Sirhan discloses that polymeric materials may be used to form the inner or outer tubular members, see column 9, lines 46-53, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. apparatus.

7. Claims 84, 85, 91 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., in view Fontirroche et al., 5,538,510, in view of Ressemann et al., and further in view of Javier, Jr. et al., 6,093,177. Sirhan et al., Fontirroche et al., and Ressemann et al. disclose the invention substantially as claimed (see above), except for the first tube having an inside surface formed of said second material proximate said bonding region and said inside surface being formed of said first material distal of said bonding region.

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However, Javier, Jr. et al. discloses that relative flexibility or the inverse stiffness of the various shaft sections of a catheter may be achieved by selecting different materials. "[T]he material used in the intermediate shaft section may be inherently more flexible than a different material used in the proximal or distal shaft sections", see column 2, lines 5-15. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide different materials on different shaft sections of the Sirhan et al. catheter in order to achieve the desired flexibility of the catheter shaft sections as may be necessary for a particular treatment of a patient

8. Claims 86, 92 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., in view of Ressemann et al., and further in view of Javier, Jr. et al., 6,093,177, further in view of Fontirroche et al., 5,538,510, and further in view of Berg et al., 5,792,116.

Although Sirhan in view of Javier and further in view of Fontirroche disclose the invention substantially as claimed, they however do not disclose the first tube being formed of PEBA distal of said tie-layer.

Berg et al. however discloses PEBA as a known polymer used to form catheters, see column 6, line 8. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device.

### ***Response to Arguments***

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

With respect to the newly added limitations, the bonding portion, i.e., the tie-layer portion, in the Sirhan et al. catheter is considered to be disposed between a proximal portion and a distal portion of a tube wall of said first tube, as claimed by Applicant. (Applicant has not specifically defined where the proximal portion and distal portion begins and ends.)

Also, the tie-layer is considered to be disposed at an angle relative to said tube wall. (Applicant has not specifically defined whether the angle is 90 degrees or 180 degrees, for example.)

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L. 

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1890/641